

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division**

OUTSOURCING FACILITIES
ASSOCIATION, et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION, et al.,

Defendants.

Civil Action No. 4:24-cv-00953-P

Plaintiffs' Motion for a Preliminary Injunction and Stay Pending Review

Pursuant to Federal Rule of Civil Procedure 65(a) and 5 U.S.C. § 705, Plaintiffs Outsourcing Facilities Association (“OFA”) and North American Custom Laboratories, LLC, doing business as FarmaKeio Custom Compounding (“FarmaKeio”), hereby move the Court to enter (1) a preliminary injunction prohibiting the Food and Drug Administration (“FDA”) from taking action against OFA members and FarmaKeio based on their compounding of the drug ingredient tirzepatide pending final judgment in this case and (2) a stay pending conclusion of the review proceedings in this case of the effective date of the FDA’s action removing tirzepatide injection products from drug shortage list maintained pursuant to 21 U.S.C. § 356e.

For either a preliminary injunction or stay, Plaintiffs “must establish (1) a likelihood of success on the merits; (2) a substantial threat of irreparable injury; (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted; and (4) that the grant of an injunction will not disserve the public interest.” *Ladd v. Livingston*, 777 F.3d 286, 288 (5th Cir. 2015) (quoting *Trottie v. Livingston*, 766 F.3d 450, 452 (5th Cir. 2014)); *see also Airlines for America v. Dep’t of Trans.*, 110 F.4th 672, 674 (5th Cir. 2024) (applying 5 U.S.C. § 705). As explained in the attached memorandum of law, Plaintiffs have established these elements, and preliminary relief is proper to prevent irreparable harm and preserve the status quo

until final judgment can be rendered in this case. This Motion is accompanied by a memorandum of law in support and an appendix.

The Court should decline to impose a security requirement under Federal Rule of Civil Procedure 65(c). The amount of security required “is a matter for the discretion of the trial court,” and the Fifth Circuit has held district courts have discretion to “require no security at all.” *Kaepa, Inc. v. Achilles Corp.*, 76 F.3d 624, 628 (5th Cir. 1996) (citing *Corrigan Dispatch Company v. Casa Guzman*, 569 F.2d 300, 303 (5th Cir. 1978)). FDA will not suffer financial harm from an injunction that would make a security requirement proper, so no security requirement is appropriate in this case.

Dated: January 28, 2025

/s/ Ty Doyle

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Certificate of Service

I hereby certify that this document, filed through the CM/ECF system on this day, will be sent via electronic mail to the registered participants as identified on the Notice of Electronic Filing.

Dated: January 28, 2025

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